

APPLICATION UNDER UNITED STATES PATENT LAWS

Invention: **HEADGEAR FOR USE WITH A PATIENT INTERFACE DEVICE**

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This is a:

- ☐ Provisional Application
- ☒ Regular Utility Application
- ☐ Continuing Application
- ☐ PCT National Phase Application
- ☐ Design Application
- ☐ Reissue Application
- ☐ Substitute Specification
- ☐ Marked-Up Specification

SPECIFICATION

HEADGEAR FOR USE WITH A PATIENT INTERFACE DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[01] This application claims priority under 35 U.S.C. § 119(e) from provisional U.S. patent application no. 60/402,336 filed August 9, 2002, the contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[02] The present invention generally relates to a headgear, and, more particularly, to a headgear having a universal fit for a patient interface device, such as a gas delivery mask, and to a system for supplying a flow of gas to a patient that incorporates such a headgear.

2. Description of the Related Art

[03] There are numerous situations where it is necessary or desirable to deliver a flow of breathing gas non-invasively to the airway of a patient, i.e., without intubating the patient or surgically inserting a tracheal tube in their esophagus. For example, it is known to ventilate a patient using a technique known as non-invasive ventilation. It is also known to deliver continuous positive airway pressure (CPAP) or variable airway pressure, which varies with the patient's respiratory cycle, to treat a medical disorder, such as sleep apnea syndrome, in particular, obstructive sleep apnea (OSA), or congestive heart failure.

[04] Non-invasive ventilation and pressure support therapies involve the placement of a patient interface device, which is typically a nasal mask that covers the nose, a nasal/oral mask that covers the nose and mouth, or full face mask that covers the patient face, on the face of a patient. The patient interface device interfaces the ventilator or pressure support device with the airway of the patient, so that a flow of breathing gas can be delivered from the pressure/flow generating device to the airway of the patient. It is known to maintain such masks on the face of a wearer by a headgear having upper and lower straps, each having opposite ends threaded through connecting elements provided on the opposite sides and top of a mask. Because such masks are typically worn for an

extended period of time, it is important the headgear maintain the mask in a tight enough seal against a patient's face without discomfort.

[05] One such headgear is disclosed in U.S. Patent No. 5,517,986 which is assigned to Respironics, Inc. of Pittsburgh, PA, the assignee of the present application. The headgear of U.S. Patent No. 5,517,986 which is incorporated by reference herein, includes a cap-like headpiece adapted to fit the crown and back of a patient's head. Lower straps provide a two-point connection with a gas delivery mask. Depending straps depending from the headpiece are connected to and moveable relative to the lower straps. Additionally, a pair of upper straps can be used to provide a four-point connection with the gas delivery mask if needed.

[06] Another such headgear 10 manufactured by Respironics, Inc. is illustrated in FIG. 1. Headgear 10 comprises five straps 12, 14, 16, 18, 20 extending in a star-like manner from a rear joining piece 22, which is positionable along the rear portion of a patient's head. The three uppermost straps 12, 14, 16 are adapted to fit on the patient's head. Center top strap 12 extends from joining piece 22 across the top of the patient's head to the patient's forehead. Upper side straps 14, 16 on either side of top strap 12 extend from joining piece 22 along the sides of a patient's head above the ears to attach to top strap 12 at the patient's forehead. Top strap 12 includes a pair of elongated openings 24 through which upper side straps 14, 16 are threaded.

[07] All of the straps include two components of a hook and loop fastener such as VELCRO. The exterior of the straps include a loop fastener portion, and a hook fastener tab portion 26 is attached to the end of each strap. When securing or fastening, the end of each upper side strap 14, 16 is bent back on itself to adhere hook fastener tab portion 26 to the exterior of the straps including the loop fastener portion. More specifically, hook fastener tab portion 26 of top strap 12 is adapted to be threaded through a connecting element of the gas delivery mask and then bent back on itself to adhere the hook fastener tab portion to the exterior loop fastener portion.

[08] Lower connecting straps 18, 20 are adapted to be brought forward from rear joining piece 22 beneath the patient's ear and threaded through connecting elements

on either side of the gas delivery mask. Tab portions 26 are bent back to adhere to the exterior loop fastener portion of lower connecting straps 18, 20.

[09] Conventional headgear 10 provides a convenient three-point headgear yet lacks adjustability in the cross direction of the head. Further, headgear 10 lacks the ability to prevent top strap 12 from shifting on the patient's head in use. Therefore, a need exists for a headgear which is easy to use and adjust.

SUMMARY OF THE INVENTION

[10] Accordingly, the present invention provides a universal headgear that creates an effective seal between a gas delivery mask and a patient and that overcomes the shortcomings of conventional headgear. The present invention further provides a headgear that is comfortable to the patient and fits a wide range of head sizes.

[11] The headgear of the present invention includes a halo-like headband formed from an elastomeric material. The elastomeric headband having contoured panels allows the device to fit most people without circumference length adjustment. The halo headband is designed to maintain a substantially frusto-conical shape when worn. It rests and secures on the head at different positions with respect to the circumference length. The present invention preferably includes an adjustable crossover strap on the top connecting the contoured panels. The crossover strap is adapted to hold the halo headband in position. The crossover strap helps prevent the headband from falling out of position. This is most notable in patients with small head circumferences. Besides the three-point connecting strap adjustment, the crossover strap is the only other adjustment needed. The headpiece further includes connecting straps to adjustably connecting the headgear to a patient interface or gas delivery mask.

[12] The present invention further comprises an assembly including a headgear and a gas delivery mask, and to a system for supplying a flow of gas to a patient that incorporates such a headgear. The headgear of the present invention fits a wide range of head sizes and shapes, is easy to use and provides increased stability.

[13] These and other objects, features and characteristics of the present invention, as well as the methods of operation and functions of the related elements of structure and the combination of parts and economies of manufacture, will become more

apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

- [14] FIG. 1 is a plan view of the headgear according to the prior art;
[15] FIG. 2 is a plan view of the headgear according to the present invention;
[16] FIG. 3 is a front view of a patient wearing the headgear of FIG. 2 with a nasal mask;
[17] FIG. 4 is a side view of a patient wearing the headgear of FIG. 2; and
[18] FIG. 5 is a rear perspective view of a patient wearing the headgear of FIG. 2.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS OF THE INVENTION

- [19] FIGS. 2-5 illustrate an exemplary embodiment of a headgear 30 according to the principles to the present invention. Headgear 30 includes a rear joining piece 32 having lower corners 34 from which a pair of lower connecting straps 36, 38 extend. A pair of contoured panels 40, 42 extend from upper corners 44 of the joining piece. Contoured panels 40, 42 extend from rear joining piece 32, which is positionable along the rear of a patient's head to a Y-shaped front joining piece 46, which is positionable along the patient's forehead. In use, the contoured panels extend along the sides of the patient's head above the ears, as shown, for example, in FIGS. 3-5.
- [20] Contoured panels 40, 42 are crescent or arch-shaped having an upper edge 48 having a concave curvature and a lower edge 50 having a convex curvature. Each contoured panel 40, 42 further has a rear joining edge 52, which is connected to rear joining piece 32 and a front joining edge 54, which is connected to front joining piece 46. Rear joining edge 52 of each panel is preferably longer in length than front joining edge

54, so that each contoured panel 40, 42 generally tapers from its rear joining edge 52 to its front joining edge 54. Joining pieces 32 and 46 and contoured panels 40 and 42 are preferably stamped from material using a die cut process so that the resulting pieces are flat. However, when positioned on the head, the contoured panels and joining pieces form a substantially truncated conical or frusto-conical shaped headpiece. It is to be understood, however, that the present invention contemplates forming joining pieces 32 and 46 and contoured panels 40 and 42, or any combination thereof, as a single piece of material so that these pieces are integral with one another. An upper circumference following the upper edges 48 of the contoured panels 40, 42 is shorter in length than a lower circumference following the lower edges 50 of the contoured panels. The substantially frusto-conical shape and stretchiness of the headpiece allow the panels to fit a wide range of patients' heads.

[21] Headgear 30 optionally, yet preferably, has an adjustable crossover strap 56 adapted to fit across the top of the patient's head from a middle portion 58 of one contoured panel to a middle portion 58 of the other contoured panel. The crossover strap 56 is attached at one end 60 to one of the contoured panels, e.g., near upper edge 48. A loop 62 is attached to the other of the contoured panels. An exterior 64 (FIG. 5) of crossover strap 56 includes the loop fastener portion of a hook and loop fastener, such as VELCRO while an end tab portion 66 includes the hook portion. The end tab portion 66 (FIG. 4) is threaded through loop 62 and bent back on itself to adhere the hook portion to the loop portion.

[22] The present invention contemplates other means of attaching and adjusting the crossover strap as well. In an exemplary embodiment, crossover strap 56 is formed from a stretchable material and loop 62 is formed from fabric. Optional crossover strap 56 provides adjustability in the cross direction of the head as well as stability by preventing downward displacement of the headgear 30.

[23] The headgear 30 further includes an upper connecting strap 68 attached to the central portion of front joining piece 46. In use, upper connecting strap 68 depends downwardly from front joining piece 46 and across the patient's forehead (see FIGS. 3 and 4). Upper connecting strap 68 is adapted to be secured to a connecting element 70

disposed at the top of a patient interface device 72, such as a conventional gas delivery mask. Upper connecting strap 68 includes the components of a hook and loop type fastener such as VELCRO, for example, having the loop portion on an exterior 74 of upper connecting strap 68 and the hook portion on an end tab portion 76 at the end of upper connecting strap 68. End tab portion 76 of upper connecting strap 68 is threaded through connecting element 70 disposed on patient interface device 72 and then bent back on itself to adhere to the exterior loop portion 74 of upper connecting strap 68.

[24] The pair of lower connecting straps 36, 38 extend forwardly from the rear joining piece beneath the patient's ears and are adapted to be secured to connecting elements 78 disposed on the sides of patient interface device 72 (FIGS. 3 and 4). Like upper connecting strap 68, lower connecting straps 36, 38 preferably include two components of a hook and loop type fastener. For example, an exterior 80 of lower connecting straps 36, 38 includes a loop fastener portion and the hook fastener portion is disposed on an end tab portion 82 at the end of each lower connecting strap 36, 38. Thus, each lower connecting strap 36, 38 is adapted to be threaded through a connecting element 78 on the side of patient interface device 72 and then bent back on itself to adhere end tab portion 82 to exterior 80 of the lower connecting strap.

[25] Preferably, but optionally, each lower connecting strap 36, 38 includes at least one intermediary tab portion 84 having a hook fastener portion. Each intermediary tab portion 84 is attached to exterior 80 of lower connecting straps 36, 38 between end tab portion 82 and the end of the strap attached to rear joining piece 32. When fitting the headgear 30 on a smaller size head, intermediary tab portion 84, as well the end tab portion 82, is threaded through connecting element 78 of patient interface device 72. Each intermediary tab portion is bent back on itself over connecting element 78 to secure the patient interface device to the headgear. Each end tab portion 82 is also secured to exterior 80 of lower connecting strap 36, 38.

[26] The connecting straps 36, 38, 68 may be formed of an elastic material to provide for adjustment. Of course, the present invention contemplates the connecting straps 36, 38, 68 can use other forms of adjustment and connection other than hook and loop fasteners such as snaps or buckles. It should also be apparent that the other one of

the hook and loop fastener component described above could be substituted for the component disclosed.

[27] The contoured panels 40, 42 are preferably formed from a stretchy elastomeric material to allow for fitting various sized patients' heads. Preferably, the material is LYCRA laminated foam having sufficient elastic adjustability to adapt to different shaped heads as well as padding for comfort. Of course, the present invention contemplates the panels 40, 42 be made of other types of material such as NEOPRENE as long as the material provides sufficient elasticity and comfort as well as air permeability.

[28] Similarly, the rear joining piece 32 and front joining piece 46 are preferably made of an elastic lightweight air permeable material such as LYCRA laminated foam. The present invention contemplates the joining pieces 32, 46 be made of other types of material such as NEOPRENE as long as it provides sufficient elasticity and comfort.

[29] FIGS. 2-5 illustrates connection with a patient interface device 72 in the form of a nasal mask of the type disclosed in U.S. Patent No. 6,412,488, the disclosure of which is incorporated by reference herein. However, the present invention may be used with other patient interface devices, including a nasal mask, a nasal/oral mask, and a full face mask. Also, the present invention contemplates modification of the front joining piece 46 to a T-shaped piece including two connecting straps for use with four point connecting masks.

[30] In patient interface device 72 of the type shown in FIGS. 2-5, a conduit 86 that extends upwardly from the patient interface device and above the head of the patient. Note that in FIG. 3, the conduit is shown extending downwardly. While this configuration is contemplated by the present invention, it is considered desirable to anchor conduit 86 to headgear 30 for stability. To this end, a conduit stabilizer 88 is provided for stabilizing the conduit 86 relative to the headgear 30. See FIG. 4. This type of stabilizer 86 is also provided in the prior art headgear of FIG. 1 but not illustrated. Conduit stabilizer 88 comprises a loop of material 90 having a hook and loop type attachment, and an alligator type clip 92 attached to one end. Material 90 is looped

around the conduit 86 and secured with the hook and loop type attachment while alligator type clip 92 is clipped to one of contoured panels 40, 42.

[31] Patient interface device communicates a flow of breathing gas between the patient's airway and pressure generating device 94 (FIG. 4), such as a ventilator, CPAP device (FIG. 3), or variable pressure device, e.g., a BiPAP[®] device manufactured and distributed by Respirationics, Inc., in which the pressure provided to the patient varies with the patient's respiratory cycle so that a higher pressure is delivered during inspiration than during expiration. Other variable pressure devices vary the pressure of gas delivered to the patient based on the detected condition of the patient, such as whether the patient is snoring, experiencing and apnea, hypopnea, etc.

[32] Communicating a flow of breathing gas between the patient's airway and pressure generating device 94 includes delivering a flow of breathing gas to the patient from the pressure generating device 94 and exhausting a flow of gas from the patient to ambient atmosphere. The system for delivering a breathing gas to a patient according to the present invention comprises: 1) pressure or gas flow generating device 94 that produces a flow of gas; 2) conduit 86 having a first end portion operatively coupled to the gas flow generating device 94 and a second end portion, wherein the conduit carries the flow of gas from the gas flow generating device 94 during operation of the system; 3) patient interface device 72 assembly coupled to the second end portion of the conduit 86; and 4) headgear 30 as described above.

[33] Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims.